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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,185	08/03/2005	Gordon D. Ross	3593.1001-008	6460

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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
01/21/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,185	ROSS ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,14 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-4, 14, and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/23/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. The amendments filed 9/23/2010 were entered.

Response to Arguments

2. Applicants' arguments, filed 9/23/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims 1, 3-4, 14, and 16-18 are maintained rejected under 35 U.S.C. 103(a) as being unpatentable over Vetvicka et al (cited in a previous Action), Jamas et al (cited in a previous**

Action), Hortobagyi (cited in a previous Action), Sliwkowski (cited in a previous Action) as evidenced by Gelderman et al (cited in a previous Action), and Kolb et al (cited in a previous Action).

6. As amended, instant claim 1 is drawn to a method of suppressing or eliminating tumor cells, comprising administering to a subject in need of suppressing or eliminating tumor cells a **yeast** neutral soluble glucan and at least one complement activating anti-tumor antibody directed to the tumor cells or antigens of said tumor cells (the antibody being introduced via direct administration of antibody), wherein the glucan does not induce systemic release of inflammatory cytokines and the glucan and antibody together **synergistically** suppress or eliminate tumor cells.

7. As discussed in the previous Action mailed on 3/23/2010, and reiterated largely as follows, Vetvicka et al teach that iC3b-coated tumor cells are not targeted for destruction by natural killer cells (Page 50, Column 2). However, soluble β-glucans cause natural killer (NK) cells "to express potent tumoricidal activity" (Page 50, Column 2) by "priming" the CR3 receptors of NK cells "for cytotoxicity of iC3b-tumor cells that were otherwise resistant to killing" (Page 51, Column 1). Notably, Vetvicka et al also disclose that "[e]xperiments have now shown that the density of bound iC3b/C3dg on freshly isolated breast tumors is adequate for in vitro recognition and cytotoxicity of SZP-primed CR3. In experiments with mice, SZP therapy caused regression of established mammary tumors" (Page 59, Column 2). Thus, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to administer soluble β-glucans to suppress or eliminate mammary tumor cells to a subject in need thereof in view of Vetvicka et al. The skilled artisan would have been motivated to do

since Vetvicka et al teach that (1) soluble β-glucans prime NK cells for cytotoxicity of iC3b-tumor cells; (2) mammary carcinoma cells contain sufficient iC3b for recognition by CR3-primed NK cells; and (3) STZ (which similarly primes CR3 of NK cells (Page 59, Column 2)) can treat mammary tumors. Accordingly, the skilled artisan would have reasonably predicted that administration of soluble β-glucans would prime CR3 of NK cells for cytotoxicity of iC3b-tumor cells and specifically mammary carcinoma cells, thus treating mammary tumors.

8. However, Vetvicka et al do not explicitly teach the administration of **neutral** soluble glucans as recited by instant claim 1. Nor do Vetvicka et al teach the administration of at least one complement activating anti-tumor antibody as recited by instant claim 1.

9. **FIRST**, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to administer neutral soluble glucans, specifically, as opposed to soluble glucans (as taught by Vetvicka et al) in view of Jamas et al. Jamas et al disclose that the administration of soluble β-glucans (but not neutral soluble glucans) stimulate cytokines such as tumor necrosis factor (Column 2, Lines 39-55) which is "involved in infection, inflammation and **cancer**" (Column 3, Lines 14-15, emphasis added). As such, it would have been prima facie obvious to administer **neutral** soluble glucans (as taught by Jamas et al) instead of soluble glucans to suppress or eliminate mammary tumor cells (as taught by Vetvicka et al). The skilled artisan would have been motivated to do so in order to prime NK cells for cytotoxicity of iC3b-tumor cells (e.g., mammary tumor cells) while avoiding the adverse side affects caused by the stimulation of tumor necrosis factor (i.e., cancer) with a reasonable expectation of success considering that Jamas et al specifically teach that neutral soluble glucans retain "a specific subset of immunological properties common to β-glucans but uniquely do not induce production

of IL-1 and TNF in vitro or in vivo" (Column 3, Lines 45-48). As such, it is asserted that the glucan would not induce systemic release of inflammatory cytokines as recited by claim 1 as amended.

10. **SECOND**, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to also administer at least one complement activating anti-tumor antibody as recited by claim 1 for each of the following reasons: **(1)** complement activating anti-tumor antibodies, such as trastuzumab (a monoclonal antibody), are well known in the art for the treatment of cancer, including mammary carcinoma, as evidenced by Hortobagyi (Abstract). As stated in MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626, F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to also administer at least one complement activating anti-tumor antibody, specifically trastuzumab, in view of In re Kerkhoven, with a reasonable expectation of success. And **(2)**, Sliwkowski et al teach that trastuzumab activates complement, as evidenced by Gelderman et al (Page 160, Column 1, Reference 15). Since iC3b is generated during activation of the complement system (as evidenced by Kolb et al (Column 3, Lines 3-8)), the skilled artisan would have reasonably predicted that the co-administration of trastuzumab would promote iC3b coating of tumor cells, thus enhancing the targeting of neutral soluble glucan CR3-primed NK cells for cytotoxicity of the iC3b-coated tumor cells. Accordingly, it would have been prima facie

obvious to a person of ordinary skill in the art to administer a neutral soluble glucan and at least one complement activating anti-tumor antibody (trastuzumab) to a subject in need thereof.

11. Thus, for all of the foregoing reasons, instant claims 1, 3 and 16-18 are rejected.

12. Applicant's sole traversal is that "[n]othing in the combined references indicates to a skilled person that the combination of neutral soluble glucan and complement activating antibody would have a synergistic effect" (Applicant Arguments, Page 5). Yet, as noted by the court in Hoffer v. Microsoft Corp., 405 F.3d 1326 (Fed. Cir. 2005), a "whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited" (quoting Minton v. *Nat 'l Ass 'n of Securities Dealers, Inc.*, 336 F.3d 1373 (Fed. Cir. 2003)). In the instant case, the wherein clause (i.e., synergistic suppressesion or elimination of tumor cells) simply expresses the intended result of a process step positively recited (i.e., administering the combination of neutral soluble glucan and complement activating antibody to a subject in need thereof). As such, the wherein clause is not given patentable weight. As noted by the court in Verdegaal Bros., Inc. v. Union Oil Co. of Calif., 814 F.2d 628 (Fed. Cir.), cert. Denied, 484 U.S. 827 (1987), merely discovering and claiming a new benefit of an old process cannot render the process again patentable. As in Verdegaal Bros., Inc. v. Union Oil Co. of Calif., the burden of proof is limited to establishing that prior art discloses the same process. There is no additional burden of proving that the prior art recognized the agents of said process functioned in a synergistic manner, that property was inherently possessed by administration of the test compounds/agents according to the disclosed process, and, thus the prior art process reads on the claimed invention. As stated in In re Woodruff, 16 USPQ2d 1934

(Fed. Cir. 1990), "a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable."

13. It is possible that Applicant actually intends to assert **unexpected results**. If so, the following is provided as guidance: It is well settled that a showing of unexpected results is generally sufficient to overcome a prima facie case of obviousness. In re Albrecht, 514 F.2d 1389 (CCPA 1975). However, as recognized by the court in In re Schulze, 346 F.2d 600 (CCPA 1965), mere arguments are not sufficient to demonstrate unexpected results. Rather, unexpected results must be established by factual evidence by comparing the claimed invention with that of the closest prior art. In re Burckel, 592 F.2d 1175 (CCPA 1979). As discussed by the court in In re De Blauwe, 736 F.2d 699 (Fed. Cir. 1994), "the absence of tests comparing [Applicant's claimed invention] with those of the closest prior art… constitute mere argument". In the instant case, evidence of synergism may entail a greater than expected result based on the prior art and which may be evidence of nonobviousness. However, as discussed by the Court in In re Merck & Co., 800 F.2d 1091 (Fed. Cir. 1986), any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. As recognized by the court in Ex parte The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991), the differences must be greater than those which would have been expected from the prior art to an unobvious extent. Assuming this is met, however, Applicant is also reminded that "the objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support". In re Clemens, 622 F.2d 1029 (CCPA 1980). Thus, in In re Peterson, 315 F.3d 1325 (Fed. Cir. 2003), factual evidence demonstrating a greater than expected result from

the addition of 2% of an ingredient did not evidence unexpected results for the entire claimed range of about 1-3% of the ingredient. Rather, the nonobviousness of a broader range or genus can only be established by evidence based on unexpected results of a narrower range or genus when one of ordinary skill in the art would be able to determine a trend in the exemplified data allowing said artisan to reasonably extend the probative value thereof. In re Kollman, 595 F.2d 48 (CCPA 1979). In the instant case, although Applicant has not yet alleged unexpected results, it is noted that the claims are **not** drafted commensurate in scope with any potentially unexpected results to overcome the instant prima facie case of obviousness.

14. For the foregoing reasons, Applicant's argument is not considered persuasive. The rejection of claims is maintained. Since Applicant does not specifically traverse the rejection of claims 4 and 14 beyond the arguments discussed above and not considered, persuasive, those claims are also maintained rejected as follows:

15. Instant claim 4 is drawn to the method of claim 1 wherein the soluble beta glucan is administered parenterally. As disclosed by Jamas et al, "[t]he neutral soluble glucan preparation is appropriate for parenteral... administration" (Column 4, Lines 1-3). Accordingly, it would have been prima facie obvious to a person of ordinary skill in the art to administer the soluble beta glucan is parenterally

16. Instant claim 14 is drawn to the method of claim 1 wherein the neutral soluble glucan is in a single and/or triple helix conformation. Significantly, the neutral soluble glucans taught by Jamas et al are in the triple helix conformation (Column 3, Lines 54-55).

17. **Claims 1 and 3 are maintained rejected under 35 U.S.C. 103(a) as being unpatentable over Cheung (US 7,462,607 which claims benefit of 60/261,911 filed 1/16/2001; cited in a previous Action) in view of Jamas et al (cited in a previous Action)**

18. As discussed above, instant claim 1 is drawn to a method of suppressing or eliminating tumor cells comprising administering to a subject in need of suppressing or eliminating tumor cells a **yeast** neutral soluble glucan and at least one complement activating anti-tumor antibody directed to the tumor cells or antigens of said tumor cells (specifically, rituximab (claim 3) (the antibody being introduced via direct administration of antibody), wherein the glucan does not induce systemic release of inflammatory cytokines and the glucan and antibody together **synergistically** suppress or eliminate tumor cells.

19. Cheung teaches a method of suppressing or eliminating tumor cells or regressing tumor growth (including breast cancer (Column 2, Line 31)) comprising administering to a subject in need thereof barley **or yeast** (Column 31, Line 62 to Column 32, Line 12) beta-glucan (which are soluble glucans) and direct administration of 3F8 (which is a complement activating anti-tumor antibody) (Column 3, Lines 20-38). Furthermore, Cheung discloses that in another embodiment, the antibody is rituximab.

20. However, Cheung does not disclose administering a **neutral** soluble glucan wherein the glucan does not induce systemic release of inflammatory cytokines and the glucan and antibody together **synergistically** suppress or eliminate tumor cells.

21. As discussed above, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to administer **neutral** soluble glucans, specifically, as opposed to soluble glucans in view of Jamas et al. Jamas et al disclose that the

administration of soluble β-glucans (but not **neutral** soluble glucans) stimulate cytokines such as tumor necrosis factor (Column 2, Lines 39-55) which is "involved in infection, inflammation and **cancer**" (Column 3, Lines 14-15, emphasis added). As such, it would have been prima facie obvious to administer **neutral** soluble glucans (as taught by Jamas et al) instead of soluble glucans to suppress or eliminate mammary tumor cells in the invention taught by Cheung. The skilled artisan would have been motivated to do so in order to treat cancer without stimulating cytokines with a reasonable expectation of success.

22. Accordingly, instant claims 1 and 3 are rejected as prima facie obvious.

23. Applicant traverses on the sole ground that "[t]he Cheung references actually teach away from the administration of yeast beta glucan" because "Cheung discloses that… glucans, which are derived from sources such as Lentinan and yeast, were less effective than the barley derived beta glucan. Thus, a skilled person would not look to yeast derived neutral soluble glucan as disclosed in Jamas et al in place of the barley beta glucan" (Applicant Arguments, Page 5). The argument is not found persuasive since Cheung specifically states that the beta glucans can be purified from yeast (Column 29, Lines 8-11) and since Cheung also demonstrates that such glucans are effective. Although it is accurate that the yeast derived glucans were less effective than the barley derived beta glucan as argued by Applicant, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442 (CCPA 1971). "A known of obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551 (Fed. Cir. 1994). "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these

alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed" In re Fulton, 391 F.3d 1105 (Fed. Cir. 2004).

24. For the foregoing reasons, the claims are maintained rejected. The rejection of claims 1 and 3 over Cheung (US 7,507,724) is maintained for the same reasons and is reiterated as follows:

25. **Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheung (US 7,507,724 which claims benefit of 60/261,911 filed 1/16/2001; cited in a previous Action) in view of Jamas et al (cited in a previous Action)**

26. As discussed above, instant claim 1 is drawn to a method of suppressing or eliminating tumor cells comprising administering to a subject in need of suppressing or eliminating tumor cells a **yeast** neutral soluble glucan and at least one complement activating anti-tumor antibody directed to the tumor cells or antigens of said tumor cells (specifically, rituximab (claim 3) introduced via direct administration, wherein the glucan does not induce systemic release of inflammatory cytokines and the glucan and antibody together **synergistically** suppress or eliminate tumor cells.

27. As previously discussed, Cheung teaches a method of suppressing or eliminating tumor cells or regressing tumor growth (including breast cancer (Column 2, Line 31)) comprising administering a subject in need thereof Barley or yeast beta-glucan (which is a soluble glucan) and direct administration of 3F8 (which is a complement activating anti-tumor antibody) (Column 3, Lines 20-38). Furthermore, Cheung discloses that in another embodiment, the antibody is rituximab.

28. However, Cheung does not disclose administering a **neutral** soluble glucan wherein the glucan does not induce systemic release of inflammatory cytokines.

29. As discussed above, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to administer **neutral** soluble glucans, specifically, as opposed to soluble glucans in view of Jamas et al. Jamas et al disclose that the administration of soluble β-glucans (but not **neutral** soluble glucans) stimulate cytokines such as tumor necrosis factor (Column 2, Lines 39-55) which is "involved in infection, inflammation and **cancer**" (Column 3, Lines 14-15, emphasis added). As such, it would have been prima facie obvious to administer **neutral** soluble glucans (as taught by Jamas et al) instead of soluble glucans to suppress or eliminate mammary tumor cells in the invention taught by Cheung. The skilled artisan would have been motivated to do so in order to treat cancer without stimulating cytokines with a reasonable expectation of success.

30. Accordingly, instant claims 1 and 3 are rejected as prima facie obvious.

31. Applicant traverses on the sole ground that "[t]he Cheung references actually teach away from the administration of yeast beta glucan" because "Cheung discloses that… glucans, which are derived from sources such as Lentinan and yeast, were less effective than the barley derived beta glucan. Thus, a skilled person would not look to yeast derived neutral soluble glucan as disclosed in Jamas et al in place of the barley beta glucan" (Applicant Arguments, Page 5). The argument is not found persuasive since Cheung specifically states that the beta glucans can be purified from yeast (Column 29, Lines 8-11) and since Cheung also demonstrates that such glucans are effective. Although it is accurate that the yeast derived glucans were less effective than the barley derived beta glucan as argued by Applicant, disclosed examples and preferred

embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442 (CCPA 1971). "A known of obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551 (Fed. Cir. 1994). "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed" In re Fulton, 391 F.3d 1105 (Fed. Cir. 2004).

32. For the foregoing reasons, the claims are maintained rejected.

Conclusion

No new ground(s) of rejection are presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The

examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1628

/Brandon J Fetterolf/
Supervisory Patent Examiner, Art Unit 1628